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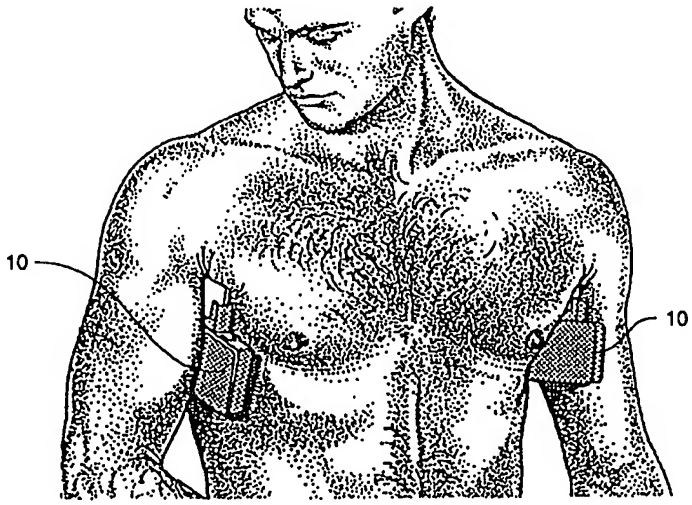

(57) Abstract

A sweat control or hyperhidrosis treatment device (10) for providing iontophoresis of antiperspirant into a region of a human body includes a DC power source (28), a controller and a pair of electrodes (12, 24). The electrodes are mounted in generally close proximity to one another and are separated by an insulating member (18). The electrodes generally carry an antiperspirant element and are responsive to a current signal through the controller. The electrodes are generally formed of aluminum and have a rough surface to increase the number of aluminum ions available for infusion into the region. The controller converts the DC signal to an AC wavform. The device further includes a pair of pads (22, 24). Each of the pads is positioned in adjacent contact with one of the electrodes and preferably carries sodium salicylate to increase the permeability of the region.

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SWEAT CONTROL SYSTEM

BACKGROUND OF THE INVENTION

This invention relates generally to a hyperhidrosis treatment device, and more particularly, to a method and apparatus for conveniently and quickly providing enhanced iontophoretic application of antiperspirant chemicals to regions of the human body in a simple and economic manner..

Treatment of excess sweating is commonly done in one of two ways. For individuals with a mild case of sweating, effective treatment may be had through the application of chemical antiperspirants. For those inflicted with unsightly excess sweating, iontophoretic treatment may be necessary. Iontophoretic treatment involves the electrical introduction of ions into the skin to block the sweat duct.

An iontophoretic device for the treatment of hands, palms and axilla is disclosed in U.S. Patent No. 4,325,367. In this device a support structure houses a pair of aluminum alloy electrodes in generally close proximity to one another as well as a source of electrical power. The electrodes are arranged so that, for example, the palm of a hand can be placed on the device and simultaneously contact both electrodes. A moisture absorbing pad is interposed between each of the electrodes and the skin of the user. In operation, the pads are moistened with water and the user places his hand on the pads. Current is applied from the electrodes, through the pads, to the user, thereby providing iontophoretic treatment.

Another iontophoretic device is disclosed in U.S. Patent No. 5,224,927. In this device, the electrical current applied between a pair of electrodes is periodically reversed at very low frequencies to mitigate tissue damage. Again, a moisture absorbing pad is interposed between each of the electrodes and the skin of the user. In operation, the treatment site may be prepared using an appropriate ionic surfactant such as an amphoteric or a cationic surfactant and electrical current in the form of a low frequency AC signal is applied to the treatment area through either water moistened pads or ionic-surfactant moistened pads.

In the well known DRIONIC compact iontophoretic device, which employs various aspects of both U.S. Patents Nos. 4,325,367 and 5,224,927, long term treatment of severe cases of hyperhidrosis is provided through a series of iontophoretic treatments. The mean-average treatment time to effectively stop sweat is approximately seven hours. The treatment regimen calls for a series of approximately half-hour individual treatment sessions spread over the course of several days. The actual length of a session and time between sessions depends on the user's tolerance to electric current. During each treatment, metal ions, *e. g.*, aluminum ions from the electrdoes, are driven deep into the eccrine sweat pores to stop sweat. The cumulative effect of the series of treatments may stop sweat for up to six weeks. Moreover, the DRIONIC device relies on amplified voltages of 60 volts and safety control circuits.

While the DRIONIC device is intended for the extremely heavy sweater, the use of such a formidable and time consuming device may be an undesirable treatment for people suffering from only a mild case of excess sweating. Most of these individuals will chose the daily use of a wide variety of well-known over-the-counter topical antiperspirants to control heavy sweating. However, a problem associated with over-the-counter topical antiperspirants is the lack of sufficient penetration into the skin of the eccrine-pore-blocking antiperspirant chemical. Thus these topical antiperspirants have limited efficacy. It has been reported that over-the-counter topical antiperspirants are effective for only about fifty percent of those who use them. The those other fifty percent receive little or no benefit from such antiperspirants. In those people who enjoy some benefit from store bought antiperspirants, this efficacy is only between twenty and forty percent.

Hence, there has been a long existing need in the art for a system capable of administering deep-penetrating iontophoretic application of antiperspirant chemicals to the human body in a short period of time. There also exists a need for such a device that operates at a low power rating and thus relatively independent of a user's tolerance for electrical current. There further exists a need for such a device that is conducive to daily use. The present invention fulfils all of these needs and others.

SUMMARY OF THE INVENTION

Briefly, and in general terms, the present invention is directed to improvements in the treatment of excess sweating and hyperhidrosis through the use of an iontophoresis administration of antiperspirant chemicals into the human body.

In a first aspect, the present invention embodies a sweat treatment device for effecting iontophoresis at a specified region of tissue. The device includes a source of electric current, a controller and a pair of electrodes. The electrodes are mounted in generally close proximity to one another and are separated by an insulating member. The electrodes carry an antiperspirant element and are responsive to the source of electrical current through the controller. One of the electrodes is connected to the source of electrical current and is arranged to act primarily as a cathode. The other electrode is connected to the source of electrical current and is arranged to act primarily as an anode. The device further includes a pair of pads. Each of the pads is positioned in adjacent contact with one of the electrodes and carries sodium salicylate. The electrodes are sized and arranged so that the tissue to be treated can extend across the insulating member and simultaneously contact both of the pads.

By carrying an appropriate salt of salicylic acid, such as sodium salicylate, the pads provide for enhanced permeability of the tissue being treated. The sodium salicylate increases the permeability of the tissue and facilitates electrical driving of the ions contained in the antiperspirant elements carried by the electrodes deeper into the tissue to precipitate the skin protein and stop sweat. Thus the device provides increase efficacy. The salicylic salt and antiperspirant chemicals would typically be replaceable.

In a more detailed aspect of the invention, the pads further carry an aluminum-based antiperspirant. In another facet, the pad antiperspirant consists of one of either aluminum-chlorohydrate or aluminum-zirconium. In yet another aspect, the electrodes are formed of sheet stock metal having an irregular, nonsmooth, surface. This nonsmooth surface creates a greater overall surface area on the electrode thereby increasing the number of antiperspirant ions available for infusion by ionthophoresis. In still another facet, the sheet stock metal consists of aluminum, aluminum alloy, magnesium or magnesium alloy. In yet another aspect, the electrodes comprise

sandblasted sheet stock metal. On other aspects the electrodes comprise powered metal formed on the sheet stock metal and the electrodes comprise aluminum oxide.

In another facet, the invention is related to an enhanced device for applying iontophoresis treatment to a selected region of a biological subject. The device includes first and second electrodes mounted in generally close proximity to one another and separated by an insulating member. The device also includes a pair of pads, each positioned in adjacent contact with one of the electrodes. Each of the pads carry an antiperspirant. The electrodes are sized and arranged so that the region to be treated can extend across the insulating member and simultaneously contact both of the pads. The device further includes an electrical energy source for conducting an electrical current through the region in a first direction from the first electrode to the second electrode; and a controller for intermittently reversing, at a relatively low frequency which prevents skin damage, between approximately 20 times per second and approximately once every three minutes, the polarity of the electrodes to cause the electrical current to flow in a second direction opposite to the first direction.

By including antiperspirant in the pads and by reversing the polarity of the electrodes to reverse the direction of current flow through the region of treatment, the device provides for a greater infusion of antiperspirant ions into the region in a set amount of time. The reason for this is that if a positively charged antiperspirant is carried by a pad when the positive half of the AC signal is driving the electrode associated with the pad, then the positive component of the antiperspirant is repelled and driven into the skin.

In more detailed facets of the invention, the antiperspirant is aluminum based. In another aspect, the antiperspirant consists of one of either aluminum-chlorohydrate or aluminum-zirconium. In still another facet, the percentage of aluminum-chlorohydrate or aluminum-zirconium contained within the antiperspirant is greater than 2%. In yet another facet, the pad further carries sodium salicylate. In a further aspect, the antiperspirant comprises an anticholinergic.

In a third aspect, the invention is related to an applicator for providing the chemical materials necessary to affect iontophoresis treatment to a selected region of a biological subject. The applicator is responsive to an AC waveform provided by a

generator. The applicator includes first and second electrodes mounted in generally close proximity to one another. The electrodes are separated by an insulating member and are responsive to the AC waveform. The applicator also includes a pair of pads. Each of the pads is positioned in adjacent contact with one of the electrodes and carries an antiperspirant. The electrodes are sized and arranged so that the region to be treated can extend across the insulating member and simultaneously contact both of the pads.

In more detailed facets of the invention, the first and second electrodes are responsive to the AC waveform such that the electrodes are of opposite polarities. In another aspect, the pads comprise a material containing the antiperspirant. In a still another facet, the pads are formed of a fiber and the antiperspirant is saturated into the pads. In other aspects, the antiperspirant comprises aluminum based chemicals and the antiperspirant comprises an anticholinergic.

In a fourth facet, the invention is related to a cosmetic method of iontophoretic infusion of antiperspirant substances into a biological subject to reduce unsightly sweating. The method comprises the step of locating a pair of electrically conductive electrodes adjacent a surface of the subject to be treated. The method also includes the steps of placing at least one antiperpirant substance and a suitable salt of salicylic acid, such as sodium salicylate, between at least one of the electrodes and the surface of the subject to be treated, and conducting an electrical current through the surface of the subject for a set duration of time. The current passes through the surface in a first direction from a first of the electrodes to a second of the electrodes on the subject. The method further includes the step of periodically and regularly reversing, at a relatively low frequency, between approximately 20 times per second and approximately once every three minutes, the polarity of the electrodes to cause the electrical current to flow in a second direction opposite to the first direction.

In a more detailed aspect of the invention, the set time duration for treatment is between 10 and 20 seconds and the low frequency is such that the polarity of the electrodes is reversed at least once during the set time duration.

These and other objects, aspects and advantages of the present invention will become apparent from the following more detailed description, when taken in

conjunction with the accompanying drawings which illustrate, by way of example, the preferred embodiments of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 illustrates an iontophoretic treatment device including a generator and an applicator constructed in accordance with the invention, and shown positioned in the axilla area of a human subject;

FIG. 2 is a plan view of a presently preferred embodiment of the iontophoretic device of FIG. 1, with a side cover of the generator being removed and portions of the applicator being broken away to illustrate internal structure;

FIG. 3 is a perspective view of the iontophoretic device of FIG. 1, showing the applicator being separated from the generator;

FIG. 4 is a top view of the generator;

FIG. 5 is a top view of the applicator;

FIG. 6 is a flow chart illustrating an iontophoretic process;

FIG. 7 is a general block diagram of the iontophoretic device of FIGS 1 and 2;

FIG. 8 is a schematic block diagram, including waveforms, of a iontophoretic device; and

FIG. 9 is a plan view of another presently preferred embodiment of an iontophoretic device, with a side cover of the generator being removed and portions of the applicator being broken away to illustrate internal structure.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the drawings, and more particularly to FIG. 1, there is shown an iontophoretic treatment device 10, of relatively simple, economical, reliable and compact construction, embodying features of the present invention. The iontophoretic treatment device 10 is shown in use in the axilla area of a suitable biological subject so that the device contacts the skin of the subject for appropriate administration of antiperspirant chemicals by iontophoretic delivery.

While the iontophoretic device 10 is shown in a presently preferred self-contained embodiment, it will be appreciated by those of ordinary skill in the art that

a larger structural and/or physical packaging unit (not shown) may be utilized, including a terminal electrode applicator for contact with the skin, and also embodying various features of the present invention.

With reference to FIGS. 2 through 5, in accordance with the present invention, an iontophoretic treatment device 10 is provided which includes an applicator 20 and a generator 39. The applicator 20 includes a pair of metallic electrodes 12, 14 mounted on a retainer 16. While the electrodes 12, 14 may be made of any metal, in a preferred embodiment they are formed of aluminum or aluminum alloy sheet stock. In another embodiment the electrodes are formed of magnesium or magnesium alloy sheet stock. In a preferred embodiment, the surface of the electrodes 12, 14 are treated to create more surface area such that more aluminum ions are available to inhibit sweat. This may be done, for example, by sandblasting the electrode 12, 14 surface or making the electrodes from powered metal. Aluminum oxide may also be added to the electrodes 12, 14. The electrodes may also be replaceable as a disposable unit.

The electrodes 12, 14 are in generally close proximity to one another and lie in generally parallel planes. The electrodes 12, 14 are separated by a relatively narrow insulating member 18. To prevent inadvertent short circuiting of the device 10 when in use, the insulating member 18 is of sufficient height to separate the pads 22, 24. Moreover, a retainer 16 is configured to ensure that no moisture from the pads 22, 24 can flow across the insulating member 18 and cause a short circuit. With this arrangement, the iontophoretic treatment device 10 can be positioned in the axilla area and held in place during treatment by the user simply lowering his arm. This arrangement has a significant advantage over prior devices in that the user's hands are relatively free during treatment, making this device particularly convenient to use.

The applicator 20 further includes a pair of moisture absorbing pads 22, 24. The pads 22, 24 are interposed between skin of the region being treated and the electrodes 12, 14 to ensure adequate electrical contact with the treatment region being treated and to distribute that electrical contact over a greater area of the region. While the pads 22, 24 can be of any suitable porous synthetic or natural fiber material, it has been found that a polyester material is preferred. Polyester electrode pads soak up water much more readily than do pads made of wool felt. In addition, polyester pads do not exhibit

the tendency to shrink, as do wool pads. Moreover, polyester pads are much more economical to supply, and do not support bacterial life as readily as wool felt pads.

As further explained hereinafter, the pads 22, 24 carry antiperspirant chemicals which, in combination with the aluminum electrodes, provide the ions to penetrate the skin to effectively block the sweat ducts. By "carry" it is meant that the pads are either 1) formed of a material containing the subject chemicals, 2) that the pads are formed of an absorbent material, such as felt, and are pre-soaked with the subject chemicals or 3) a combination of 1) and 2). In a preferred embodiment, the pads carry aluminum chlorohydrate or aluminum-zirconium. In another preferred embodiment, the pads carry an anticholinergic. In addition to the antiperspirant chemicals, the pads may also carry an appropriate salt of salicylic acid, such as sodium salicylate, to enhance aluminum ion skin penetration or permeability and hence efficacy of the device. Sodium salicylate has also been shown to have healing properties.

The generator 39 portion of the iontophoretic treatment device 10 includes an electronics package comprising an AC current generating chip 26, a battery power supply 28, electrical leads 30, 32, and a pair of electrical contacts 34, 36. The electronics package is contained within a housing 38. The combination of the electronics packaging and the housing 38 form the generator 39. The housing 38 includes two lead slots 40, 42 (FIGS 3 and 4) which provide access to the electrical contacts 34, 36 (FIG. 2). The retainer 16 portion of the applicator includes two electrical leads 44, 46 (FIG. 3) that snap into the lead slots 40, 42 on the housing 38 and into the electrical contacts 34, 36 (FIG. 2) and connect the battery supply 28 to the electrodes 12, 14. The teachings of U.S. Patent No. 5,224,927 are specifically incorporated herein.

The electronics package may also include an electrical slide switch 50. The switch projects through an upper plastic cover plate 48 of the housing 38. The switch 50 is electrically connected in the housing 38 to the AC generating chip 26. The switch 50 may be selectively moved between a "0" (off) position, to either a "LO" (low current or lower rate of ion delivery) or "HI" (high current or higher rate of ion delivery) switch positions.

The function of the switch 50 in FIG. 4 is as follows:

1) The "0" position keeps the device from functioning.

2) The "LO" treatment position infuses aluminum ions at the lowest current level at a continuous, controlled rate.

3) The "HI" treatment position infuses aluminum ions at a current level typically twice as high as the "LO" setting.

A second switch (not shown), similar to the slide switch 50, may also be provided to selectively vary the frequency of the low-frequency AC duty-cycle of the iontophoretic treatment device 10. The low-frequency AC duty-cycle operation of the device is explained below.

An LED test indicator 52 extends from the electronics package within the housing 38 through an appropriate opening in the cover plate 48, and is observable from the top of the iontophoretic treatment device 10 to confirm proper electrical operation of the system for the user. The electronics package may also include a buzzer (not shown) that is connected to a timer in the AC generating chip 26. The timer may be set to sound the buzzer at a time interval, *e. g.*, 10 seconds, in order to provide an indication to the user as to the cumulative treatment time.

Referring now to FIG. 6, the low-frequency AC duty-cycle process which facilitates the numerous advantages of the present invention is broadly illustrated and defined. In this regard, at step S1, the process calls for applying electrical current to a pair of iontophoretic electrodes of opposite polarity, such as the electrodes 12, 14 in the iontophoretic treatment device 10. In step S2, the electrical polarity and, therefore, the direction of the electrical current flowing between the electrodes 12, 14 and through the patient is periodically reversed, twice per AC cycle. This reversal of current occurs at low frequencies in the substantially critical range of approximately 10 Hz to once every three minutes, or a low frequency limit of approximately 0.0027 Hz, to achieve the advantages previously and subsequently described herein in connection with the practice of the present invention.

FIG. 7 is a basic block diagram illustrating the electronics package contained within the housing 38, wherein an electrical source 54 is directed to appropriate wave shaping and timing circuitry 56 for generating the aforedescribed low-frequency AC duty-cycle which is then directed as electrical current to iontophoretic electrodes 58 to infuse aluminum ions into the skin, *i. e.*, the electrical load in the system. It is apparent

that the various electrical subsystems indicated in FIGS. 6 and 7 can be implemented readily by those of ordinary skill in the art without the exercise of inventive skill. For example, the system illustrated in FIG. 7 may be implemented, in a presently preferred embodiment of the invention, by the more detailed system shown in FIG. 8.

Referring now to FIG. 8, there is shown a presently preferred embodiment of an overall system for providing a regulated and periodically reversible electrical current into a variable load resistance, *i. e.*, the patient. In the system, the electrical current reverses polarity and direction of flow periodically at a very low frequency. A smooth transition without discontinuity in slope is made between polarities, thus avoiding a shock sensation to the patient when reversing the electrical current. The magnitude and duty cycle of the positive and negative currents are substantially the same. The system utilizes a conventional DC power supply.

The timing of current reversals is determined by an oscillator 62, which produces at its output 64 sharp transitions between two levels, as illustrated by the waveform 66. The electrical output 64 is applied to a wave shaping network 68 to produce gradual electrical transitions, as shown by the output waveform 70 available on line 72. The electrical output of the oscillator 62, and thus the sense of the smoothed waveform, is reversed when the waveform crosses a predetermined threshold 92 determined at junction 74 under the control of a threshold detection subsystem 80. The voltage waveform 70, less the threshold 92, is applied over line 76 to a suitable voltage-to-current converter subsystem 78.

The polarity of the electrical current through a floating load 82, *e. g.*, the patient, reverses at the threshold crossing time, when the instantaneous electrical load current is zero, as illustrated by the waveform 84. A latch subsystem 86 controls a plurality of switches 88a-88d, as shown by the waveform 90, to maintain this polarity until the next threshold crossing. This produces smooth transitions between electrical current levels that are by design, substantially equal in magnitude but opposite in sign. The relatively slow rise and decay evident from leading and trailing edges of the waveform 84 provides the desirable electrical ramping up and down of each half cycle to minimize shock sensations.

The electronics package may provide for a fixed current reversal frequency. If desired, the electrical system may be modified, in a manner well known to those of ordinary skill in the art, to automatically vary the signal frequency periodically. One example of specific electrical circuitry, suitable for implementing the system shown in FIG. 8, is set forth in Appendix A attached hereto and which is specifically incorporated by reference herein.

In operation, the pads 22, 24 are soaked with water to activate the chemicals carried by the pad. The pads 22, 24 are then placed in the retainer 16, one adjacent each of the electrodes 12, 14. The retainer 16 is then placed in the axilla area. The switch 24 is moved from the "0" position to either the "LO" or "HI" position as prescribed below. Electrical current is thus applied to the electrodes 12, 14 by the generator 39 to direct ions into the eccrine duct for sweat control. The aluminum ions from the electrodes 12, 14 and from the chemicals carried by the pads 22, 24 precipitate the skin protein and plug the sweat pores.

In one embodiment of the invention, for treatment of mild cases of excess sweating, the treatment regimen comprises one 10 to 20 second session. The system is optimally operated such that at least one cycle occurs within the session. In another embodiment of the invention, for treatment of severe cases of hyperhidrosis, the treatment regimen may comprise a series of longer sessions, or 10 to 20 second sessions spread over time, depending on the user's tolerance to electrical current at either the "HI" or "LO" setting. For those individuals who are particularly sensitive to electrical current the treatment session may be only at a "LO" setting. For those who can tolerate current well the session may be at a "HI" setting. Upon completion of a treatment session, the iontophoretic treatment device 10 is switched to the "0" position. A variable potentiometer may be substituted for the switch 24 to provide more precise current adjustment.

Through repeated use of the device the amount of aluminum ions available for penetration into the skin decreases. Eventually the amount decreases to a point where the device 10 is no longer effective. In accordance with the present invention, the applicator 20 may then be separated from the generator 39, as shown in FIG. 3, and a new applicator 20 installed in its place. In this sense, the applicator may be considered

a disposable unit. It is also possible that the chemicals within the pads 22, 24 deplete before the aluminum electrodes 12, 14. In that case, a new set of pads 22, 24 may be installed in the applicator 20.

With the slow AC signal utilized in the system of the present invention, antiperspirant concentration can be increased substantially beyond the two percent level typically present in over-the-counter topical antiperspirants. With a positively charged aluminum ion antiperspirant carried by a pad 22, 24 when the positive half of the AC signal is driving the electrode 12, 14 associated with the pad, then the positive metallic ion component of the antiperspirant is repelled and driven into the skin. The sodium salicylate also contains a negative component, i.e. the salicylate ion. However, when the AC signal swings negative on the other half of the signal, the salicylate negative ion is driven into the skin. This enables substantially increased antiperspirant concentrations.

Since both electrodes are "active" with the simplified arrangement of the present invention, the device can deliver twice the amount of antiperspirant compared to a comparable DC iontophoretic device. For example, if the antiperspirant to be delivered is negative and the signal at one electrode 22, 24 is negative, then that pad delivers the antiperspirant to the skin. Simultaneously, the other electrode is positive and the same antiperspirant does not ordinarily flow.

Enhanced skin permeability occurs through the use of an appropriate salt of salicylic acid, such as sodium salicylate. The salicylate is electrically delivered into the treatment site and greatly lowers skin resistance and increases skin permeability thereby allowing for more effective iontophoretic treatment. In a preferred embodiment of the invention, the salicylate is carried, along with the antiperspirant chemicals, by the pads and is accordingly driven into the treatment region along with the antiperspirant chemicals.

With reference to FIG. 9, there is shown a second configuration of a more compact iontophoretic device 10' which incorporates aspects of the present invention. Except for the size of the generator 39' and the battery power supply 28' included therein, this configuration of an iontophoretic device 10' is generally identical to the iontophoretic device 10' of FIGS. 2 through 5. For ease in correlating the two

configurations, the numerals associated with elements of the second configuration are the same as those of the first configuration except that they are primed.

The second configuration of the iontophoretic device 10' is ideally suited for daily, short duration treatments, such as the 10 to 20 second treatment period previously described. The applicator 20' is identical to that of the first configuration device 10 (FIG. 2) and is removable from the generator 39' in the same manner as the first configuration. The battery power supply 28' (FIG. 9) comprises one 9V battery that drives the AC generator 26'. In a preferred embodiment of the second configuration, to maintain overall cost at a minimum, the frequency control present in the first configuration is absent, and an appropriate value of the frequency parameter is set during manufacture and prior to delivery to the ultimate user. With regard to frequency, the AC generator 26' is configured to ensure that at least one current reversal cycle occurs during the 10 to 20 second treatment period.

Hence, those concerned with development and use of hyperhidrosis treatment systems will appreciate that the present invention satisfies a long existing need in the art for a system capable of administering deep-penetrating iontophoretic application of antiperspirant chemicals to the human body in a short period of time, operates at a relatively low power rating and is conducive to daily use. Of course, it will be apparent that the sweat control system may be applied to any portion of the anatomy where sweating is a problem.

It will be apparent from the foregoing that, while particular forms of the invention have been illustrated and described, various modifications can be made without departing from the spirit and scope of the invention. Therefore, it is not intended that the invention be limited, except as by the appended claims.

IN THE CLAIMS:

1. A sweat control system for effecting iontophoresis at a region of tissue, said device comprising:

a source of electric current;

a controller;

a pair of electrodes mounted in generally close proximity to one another and separated by an insulating member, said electrodes carry an antiperspirant element and are responsive to said source of electrical current through said controller, one of said electrodes being connected to said source of electrical current and arranged to act primarily as a cathode, and the other of said electrodes being connected to said source of electrical current and arranged to act primarily as an anode; and

a pair of pads, each of said pads positioned in adjacent contact with one of said electrodes, each of said pads carrying sodium salicylate;

wherein said electrodes are sized and arranged so that the tissue to be treated can extend across said insulating member and simultaneously contact both of said pads.

2. The device of claim 1 wherein the pads further carry an aluminum-based antiperspirant.

3. The device of claim 2 wherein the antiperspirant consists of one of either aluminum-chlorohydrate or aluminum-zirconium.

4. The device of claim 1 wherein the electrodes are formed of sheet stock metal having an irregular, nonsmooth, surface.

5. The device of claim 1 wherein the sheet stock metal consists of aluminum, aluminum alloy, magnesium or magnesium alloy.

6. The device of claim 4 wherein the electrodes comprise sandblasted sheet stock metal.

7. The device of claim 4 wherein the electrodes comprise powdered metal formed on said sheet stock metal.

8. The device of claim 4 wherein the electrodes comprise aluminum oxide.

9. A device for applying iontophoresis treatment to a region of a biological subject, said device comprising:

first and second electrodes mounted in generally close proximity to one another and separated by an insulating member;

a pair of pads, each of said pads positioned in adjacent contact with one of said electrodes, each of said pads carrying an antiperspirant, wherein said electrodes are sized and arranged so that the region to be treated can extend across said insulating member and simultaneously contact both of said pads;

an electrical energy source for conducting an electrical current through the region in a first direction from the first electrode to the second electrode; and

a controller for intermittently reversing, at a relatively low frequency which prevents skin damage, between approximately 20 times per second and approximately once every three minutes, the polarity of said electrodes to cause said electrical current to flow in a second direction opposite to said first direction.

10. The device of claim 9 wherein the antiperspirant is aluminum based.

11. The device of claim 10 wherein the antiperspirant consists of one of either aluminum-chlorohydrate or aluminum-zirconium.

12. The device of claim 11 wherein the percentage of aluminum-chlorohydrate or aluminum-zirconium contained within the antiperspirant is greater than 2%.

13. The device of claim 9 wherein the antiperspirant comprises an anticholinergic.

14. The device of claims 9 through 13 wherein the pad further carries sodium salicylate.

15. An applicator for providing the chemical materials necessary to affect iontophoresis treatment to a region of a biological subject, said applicator responsive to an AC waveform provided by a generator, said applicator comprising:

first and second electrodes mounted in generally close proximity to one another and separated by an insulating member, said electrodes responsive to said AC waveform; and

a pair of pads, each of said pads positioned in adjacent contact with one of said electrodes, each of said pads carrying an antiperspirant, wherein said electrodes are sized and arranged so that the region to be treated can extend across said insulating member and simultaneously contact both of said pads.

16. The applicator of claim 15 wherein the first and second electrodes are responsive to the AC waveform such that the electrodes are of opposite polarities.

17. The applicator of claim 15 wherein the pads comprise a material containing the antiperspirant.

18. The applicator of claim 15 wherein the pads are formed of a fiber and the antiperspirant is saturated into the pads.

19. The device of claim 15 wherein the antiperspirant comprises aluminum based chemicals.

20. The device of claim 19 wherein the antiperspirant comprises aluminum-chlorohydrate.

21. The device of claim 19 wherein the antiperspirant comprises aluminum-zirconium.

22. The device of claim 15 wherein the antiperspirant comprises an anticholinergic.

23. The device recited in any of claims 9-21 or 22, and further including with said antiperspirant a salt of salicylic acid.

24. The device of claim 15 wherein the electrodes are formed of sheet stock metal having an irregular, nonsmooth, surface area.

25. The device of claim 23 wherein the sheet stock metal consists of aluminum, aluminum alloy, magnesium, or magnesium alloy.

26. The device of claim 23 wherein the electrodes comprise sandblasted sheet

stock metal.

27. The device of claim 23 wherein the electrodes comprise powered metal formed on said sheet stock metal.

28. The device of claim 23 wherein the electrodes comprise aluminum oxide.

29. A method of iontophoretic infusion of antiperspirant substances into a biological subject, comprising the steps of:

locating a pair of electrically conductive electrodes adjacent a surface of said subject to be treated;

placing at least one antiperpirant substance and sodium salicylate between at least one of said electrodes and said surface of said subject to be treated; and

conducting an A.C. electrical current through said surface of said subject for a set duration of time, said current passing through said surface in a first direction from a first of said electrodes to a second of said electrodes on said subject.

30. The method of claim 29, including:

periodically and regularly reversing, at a relatively low frequency, between approximately 20 times per second and approximately once every three minutes, the polarity of said electrodes to cause said electrical current to flow in a second direction opposite to said first direction.

31. The method of either claim 29 or claim 30 wherein said set time duration is between 10 and 20 seconds and said low frequency is such that the polarity of said electrodes is reversed at least once during said set time duration.

32. The method of either claim 29 or claim 30 wherein the electrodes are

formed of sheet stock metal having an irregular, nonsmooth, surface area.

33. The method of claim 32 wherein the sheet stock metal consists of aluminum, aluminum alloy, magnesium, or magnesium alloy.

34. The method of either of claims 29 or 30 wherein the antiperspirant comprises an aluminum-based chemical.

35. The device of claim 34 wherein the aluminum-based chemical consists of one of either aluminum-chlorohydrate or aluminum-zirconium.

36. A sweat control treatment system, comprising:

a source of electric current;

a controller;

electrode means connected to said controller; and

a preparation of sodium salicylate adjacent said electrode means and adapted to be delivered to a treatment site to enhance delivery of additional metallic ions to said treatment site.

37. The device of claim 36 wherein the preparation further includes an aluminum-based antiperspirant.

38. The device of claim 37 wherein the antiperspirant consists of one of either aluminum-chlorohydrate or aluminum-zirconium.

39. The device of claim 36 wherein said electrode means are formed of sheet stock metal having an irregular, nonsmooth, surface.

40. The device of claim 36 wherein the sheet stock metal consists of aluminum, aluminum alloy, magnesium or magnesium alloy.

41. The device of claim 39 wherein said electrode means comprises sandblasted sheet stock metal.

42. The device of claim 39 wherein said electrode means comprises powdered metal formed on said sheet stock metal.

43. The device of claim 39 wherein said electrode means comprises aluminum oxide.

44. In a system for sweat control, the combination comprising:

an iontophoretic delivery unit;

and a preparation of an antiperspirant including a salt of salicylic acid adapted for delivery to a subject by said iontophoretic delivery device.

45. A system as recited in claim 44 wherein said iontophoretic delivery device provides a low frequency A.C. signal to deliver said preparation.

46. A system as set forth in claim 45 wherein said A.C. signal is in the range of 10 Hz - 0.0027 Hz.

47. A system as recited in either of claims 44, 45 or 46 wherein said preparation includes sodium salicylate.

48. A system as recited in either of claims 44, 45 or 46 wherein said preparation includes an anticholinergic substance.

49. A system as recited in either of claims 44, 45 or 46 wherein said preparation includes aluminum chlorohydrate.

50. A system as recited in either of claims 44, 45 or 46 wherein said preparation includes aluminum-zirconum.

51. A method for sweat control, comprising:

providing a preparation of an antiperspirant including a salt of salicylic acid adapted for delivery to a subject by iontophoresis; and

delivering said preparation to a selected site on said subject by iontophoresis.

52. A method as recited in claim 51, wherein said iontophoresis includes delivery by low frequency A.C. current.

53. For use in a system for hyperhidrosis control, a replaceable antiperspirant unit, comprising:

a preparation of an antiperspirant including a salt of salicylic acid adapted for delivery by an iontophoretic delivery device.

54. A unit as recited in claim 53, wherein said preparation includes sodium salicylate.

55. A unit as recited in either of claims 54 or 55, wherein said preparation includes aluminum chlorohydrate.

56. A unit as recited in either of claims 54 or 55, wherein said preparation includes aluminum-zirconum.

57. A unit as recited in either of claims 54 or 55, wherein said preparation includes an anticholinergic.

58. A unit as set forth in any of claims 53-56 or 57 wherein said preparation is provided in the form of a pad.

59. For use with an iontophoretic hyperhidrosis treatment device, a mixture comprising:

antiperspirant including a salt of salicylic acid adapted for delivery by an iontophoretic delivery device.

60. In a system for hyperhidrosis control, the combination comprising:

an iontophoretic delivery unit;

and a preparation of an antiperspirant including a salt of salicylic acid adapted for delivery by said iontophoretic delivery device.

61. For use with an iontophoretic hyperhidrosis control device, the combination comprising:

a mixture of an antiperspirant including a salt of salicylic acid adapted for delivery by said iontophoretic delivery device; and

metal output electrodes having extended surfaces.

62. A combination as set forth in claim 61, wherein the antiperspirant comprises aluminum based chemicals.

63. A combination as set forth in claim 61, wherein the antiperspirant comprises aluminum chlorohydrate.

64. A combination as set forth in claim 61, wherein the antiperspirant comprises aluminum-zirconium.

65. A combination as set forth in claim 61, wherein the antiperspirant comprises anticholinergic.

66. A combination as set forth in claim 61, wherein the electrodes are formed of sheet stock metal having an irregular, nonsmooth, surface area.

67. A combination as set forth in claim 66, wherein the sheet stock metal consists of aluminum, aluminum alloy, magnesium, or magnesium alloy.

68. A combination as set forth in claim 66, wherein the electrodes comprise sandblasted sheet stock metal.

69. A combination as set forth in claim 66, wherein the electrodes comprise powdered metal formed on said sheet stock metal.

70. A combination as set forth in claim 66, wherein the electrodes comprise aluminum oxide.

71. For use in a system for sweat control, a replaceable antiperspirant unit, comprising:

a preparation of an antiperspirant including a salt of salicylic acid adapted for delivery by an iontophoretic delivery device.

72. A unit as recited in claim 71, wherein said preparation includes sodium salicylate.

73. A unit as recited in either of claims 72 or 73, wherein said preparation includes aluminum chlorohydrate.

74. A unit as recited in either of claims 72 or 73, wherein said preparation includes aluminum-zirconum.

75. A unit as recited in either of claims 72 or 73, wherein said preparation includes an anticholinergic.

76. A unit as set forth in any of claims 71-74 or 75 wherein said preparation is provided in the form of a pad.

77. For use with an iontophoretic treatment device, a mixture comprising:

antiperspirant including a salt of salicylic acid adapted for delivery by an iontophoretic delivery device.

78. In a system for hyperhidrosis control, the combination comprising:

an iontophoretic delivery unit;

and a preparation of an antiperspirant including a salt of salicylic acid adapted for delivery by said iontophoretic delivery device.

79. For use with an iontophoretic sweat control device, the combination comprising:

a mixture of an antiperspirant including a salt of salicylic acid adapted for delivery by said iontophoretic delivery device; and

metal output electrodes having extended surfaces.

80. A combination as set forth in claim 79, wherein the antiperspirant comprises aluminum based chemicals.

81. A combination as set forth in claim 79, wherein the antiperspirant comprises aluminum chlorohydrate.

82. A combination as set forth in claim 79, wherein the antiperspirant comprises aluminum-zirconium.

83. A combination as set forth in claim 79, wherein the antiperspirant comprises anticholinergic.

84. A combination as set forth in claim 79, wherein the electrodes are formed of sheet stock metal having an irregular, nonsmooth, surface area.

85. A combination as set forth in claim 84, wherein the sheet stock metal consists of aluminum, aluminum alloy, magnesium, or magnesium alloy.

86. A combination as set forth in claim 84, wherein the electrodes comprise sandblasted sheet stock metal.

87. A combination as set forth in claim 84, wherein the electrodes comprise powdered metal formed on said sheet stock metal.

88. A combination as set forth in claim 84, wherein the electrodes comprise aluminum oxide.

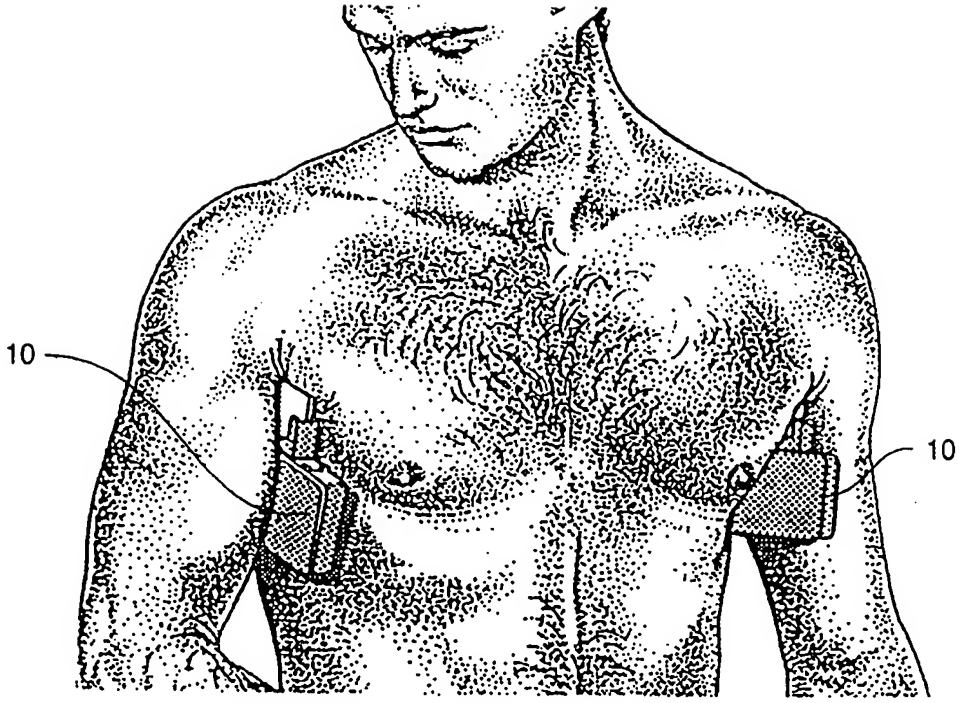


FIG. 1

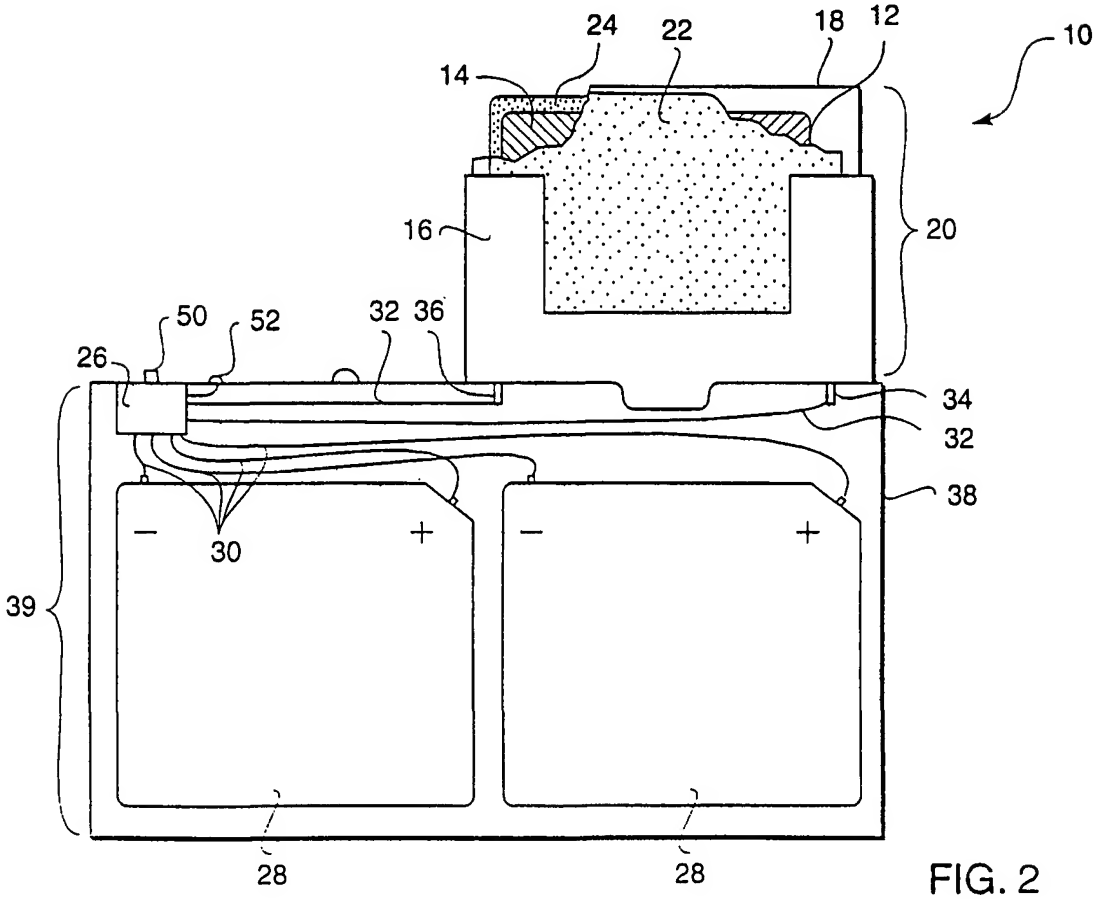


FIG. 2

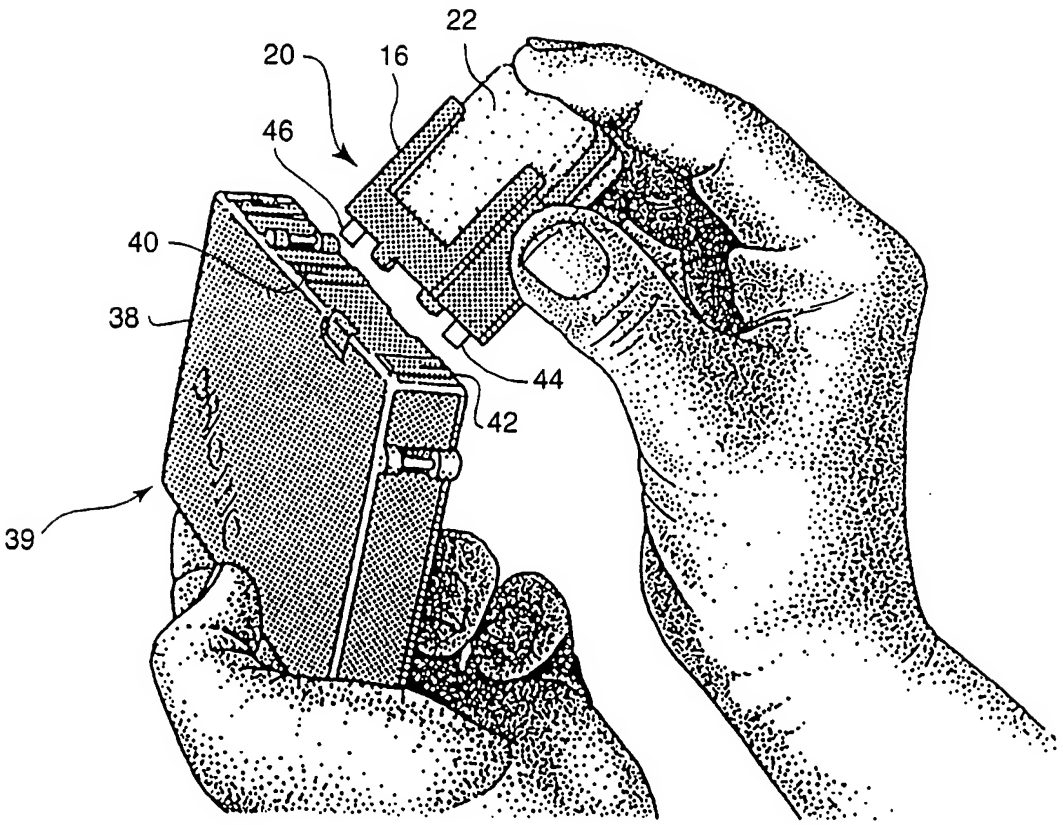


FIG. 3

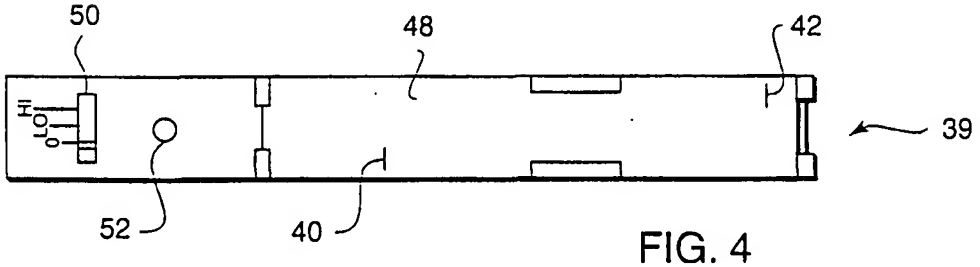


FIG. 4

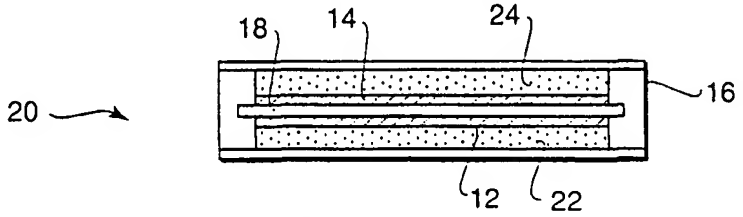


FIG. 5

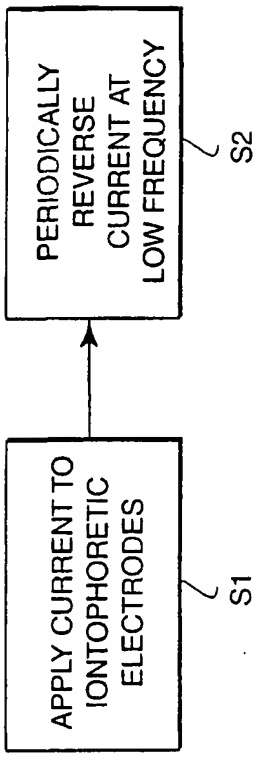

APPLY CURRENT TO IONTOPHORETIC ELECTRODES
S1
PERIODICALLY REVERSE CURRENT AT LOW FREQUENCY
S2

FIG. 6

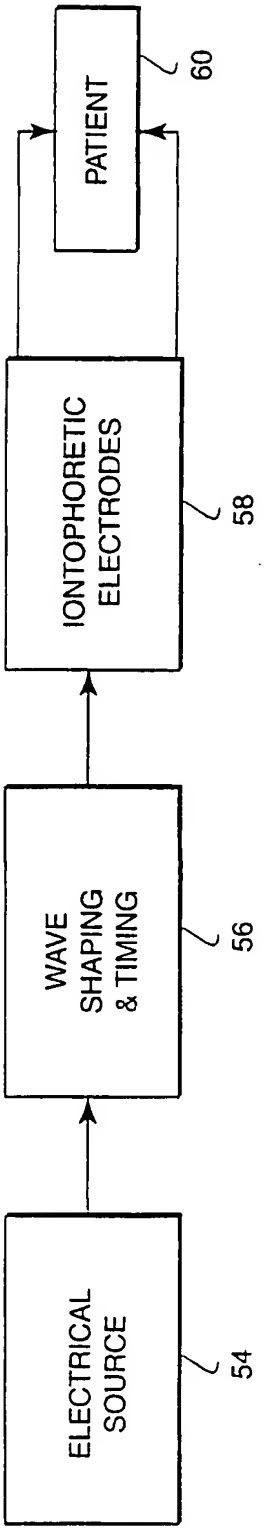

ELECTRICAL SOURCE
54
WAVE SHAPING & TIMING
56
IONTOPHORETIC ELECTRODES
58
PATIENT
60

FIG. 7

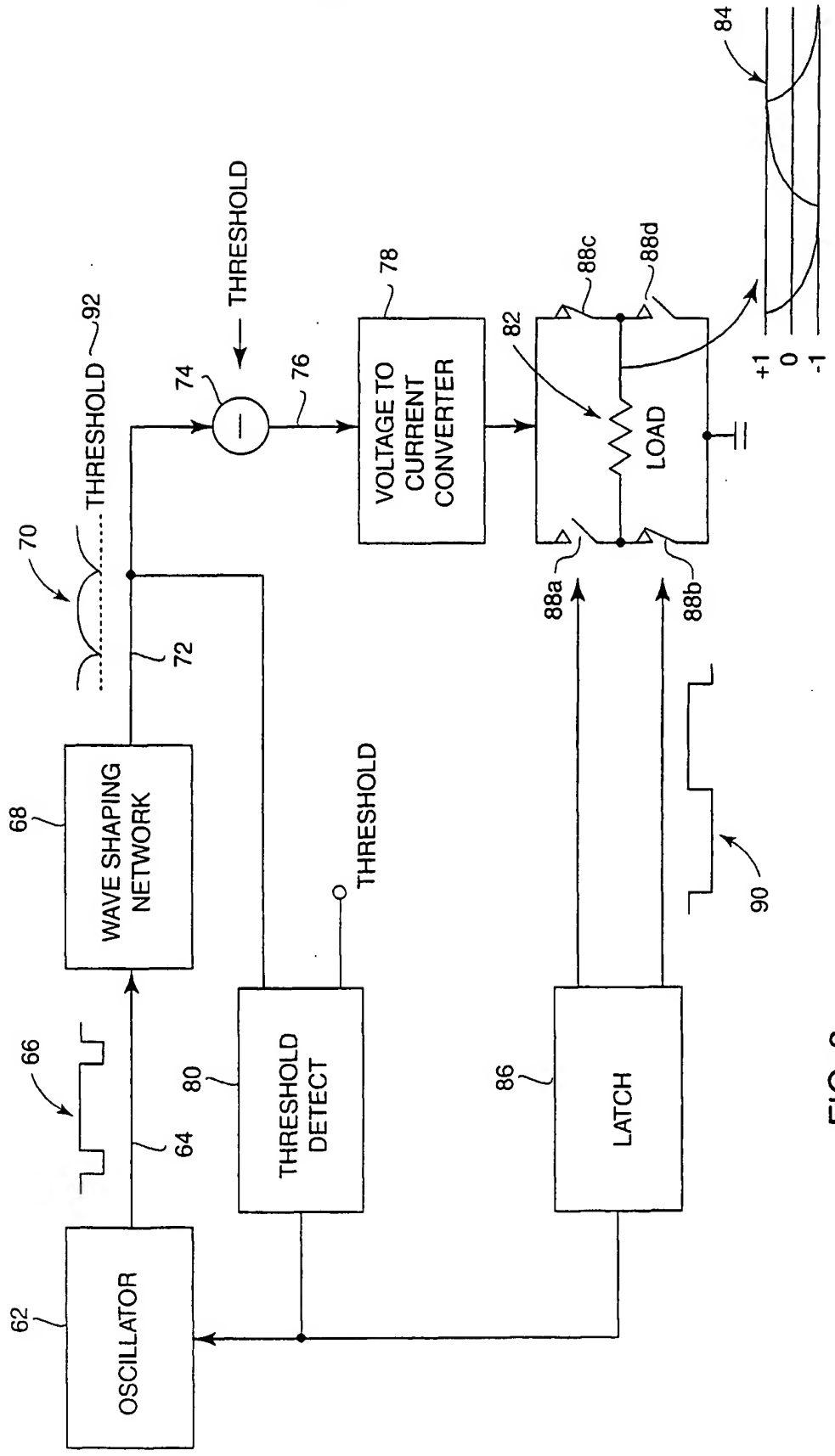

OSCILLATOR
62
66
64
WAVE SHAPING NETWORK
68
70
THRESHOLD
92
72
THRESHOLD DETECT
80
THRESHOLD
74
76
VOLTAGE TO CURRENT CONVERTER
78
82
LOAD
88a
88b
88c
88d
84
+1
0
-1
LATCH
86
90

FIG. 8

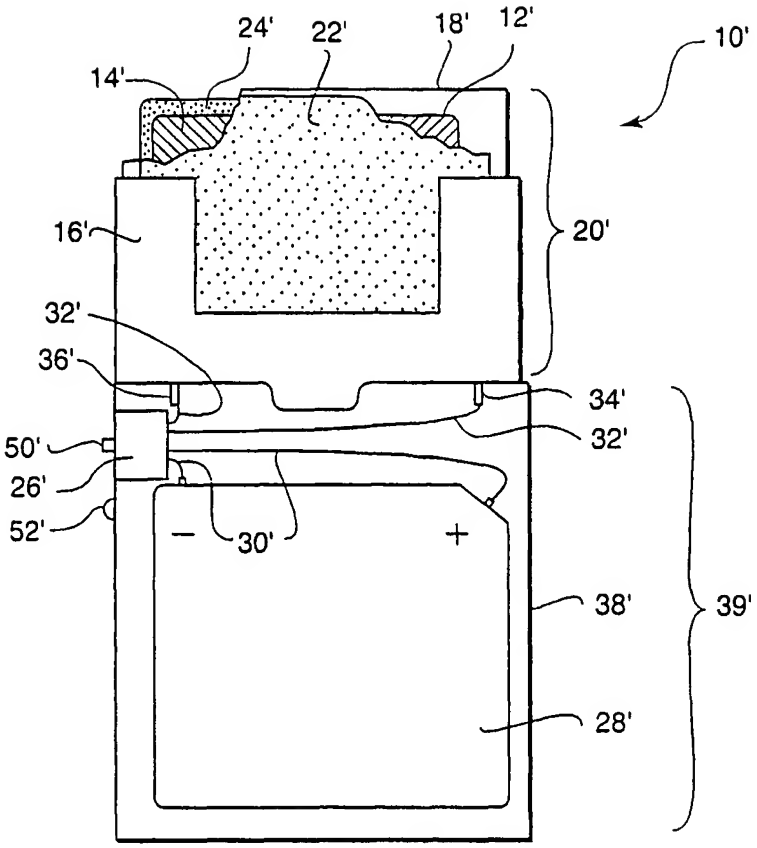
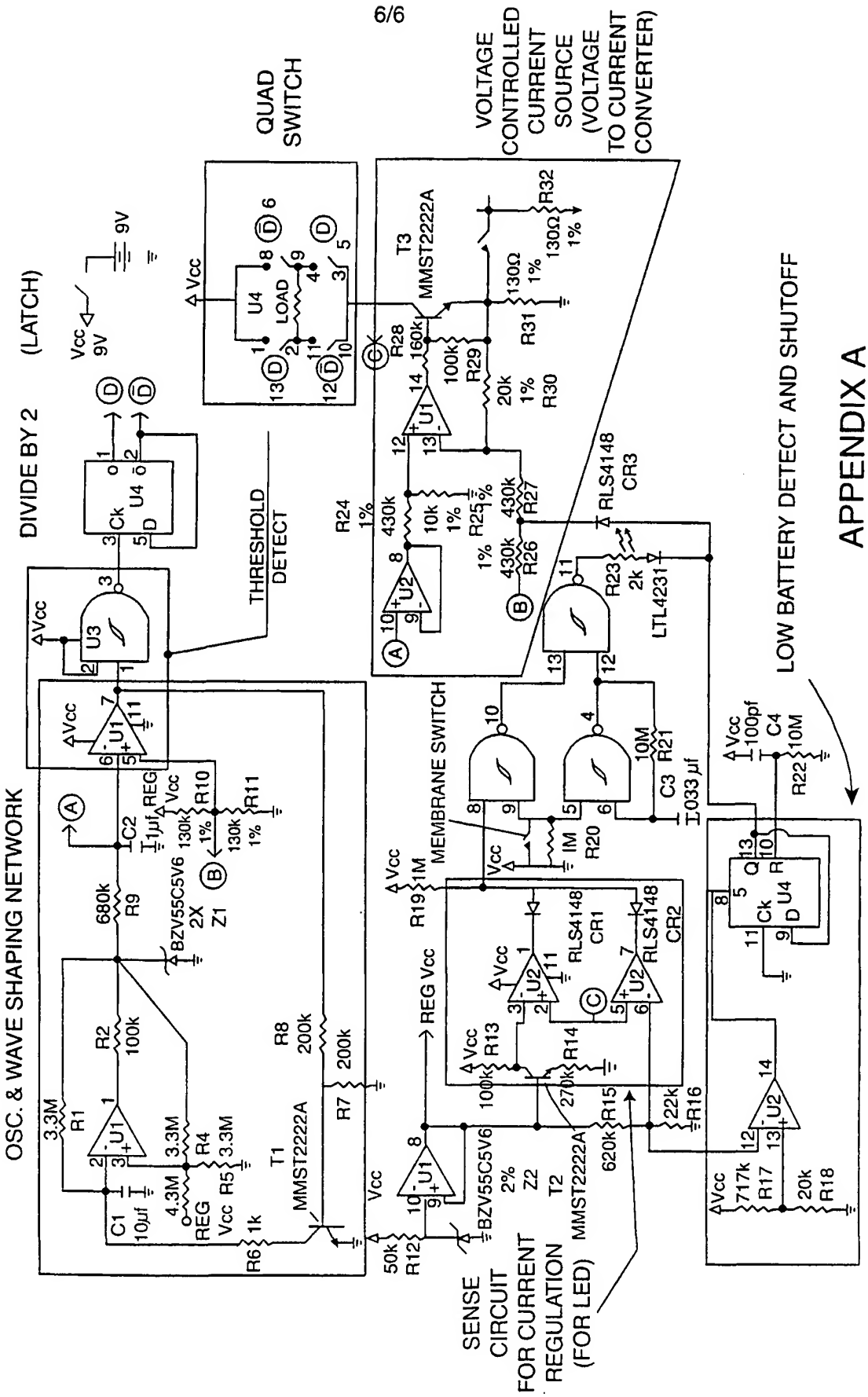


FIG. 9


APPENDIX A
OSC. & WAVE SHAPING NETWORK
DIVIDE BY 2 (LATCH)
THRESHOLD DETECT
QUAD SWITCH
VOLTAGE CONTROLLED CURRENT SOURCE (VOLTAGE TO CURRENT CONVERTER)
LOW BATTERY DETECT AND SHUTOFF
MEMBRANE SWITCH
SENSE CIRCUIT FOR CURRENT REGULATION (FOR LED)
9V
Vcc
REG Vcc
U1
U2
U3
U4
T1
T2
T3
MMST2222A
BZV55C5V6
RLS4148
LTL4231
LOAD
R1
R2
R3
R4
R5
R6
R7
R8
R9
R10
R11
R12
R13
R14
R15
R16
R17
R18
R19
R20
R21
R22
R23
R24
R25
R26
R27
R28
R29
R30
R31
R32
C1
C2
C3
C4
CR1
CR2
CR3
Z1
Z2

INTERNATIONAL SEARCH REPORT

Int. .tional Application No
PCT/US 00/06860

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61N1/32

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
WPI Data, EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 224 927 A (TAPPER ROBERT) 6 July 1993 (1993-07-06) cited in the application column 7, line 39 -column 15, line 55; figures	1,9,15
A	GB 2 030 453 A (TAPPER R) 10 April 1980 (1980-04-10) page 2, line 2 -page 3, line 120; figures	1,9,15, 36,44, 53, 59-61, 71,77-79

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
14 July 2000	21/07/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Rakotondrajaona, C

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Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Int. tional Application No
PCT/US 00/06860

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	DE 41 37 960 A (SCHAUF GERHARD PROF) 27 May 1993 (1993-05-27) column 1, line 47 -column 2, line 66; figures	1,9,15, 36,44, 53, 59-61, 71,77-79
A	US 5 008 111 A (BODOR NICHOLAS) 16 April 1991 (1991-04-16) column 2, line 39 -column 4, line 21	1,9,15, 36,44, 53, 59-61, 71,78,79
A	US 4 325 367 A (ROBERT TAPPER) 20 April 1982 (1982-04-20) cited in the application column 2, line 28 -column 3, line 23; figures	1,9,15, 36

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Int .tional Application No
PCT/US 00/06860

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